

Remarks

Claims 1-36 and 41 are canceled and new claims 44-45 are added herein. Claims 37-40 and 42-45 are pending in the application. Applicants reserve the right to claim the subject matter of claims 1-36 in continuing or divisional applications. Support for the new claim 44 is found, *inter alia*, in Table 1. Support for new claim 45 is found, *inter alia*, at page 80, paragraph [0241] of the specification.

I. The Specification

The Examiner has objected to the specification for containing nucleic acid or amino acid sequence data not identified by SEQ ID NO as required by 37 C.F.R. §§ 1.821 through 1.825. Applicants thank the Examiner for pointing the oversight. As amended herein, all of the sequences in the specification are identified by SEQ ID NOs. In addition, a Sequence Listing is being filed electronically along with this reply. Applicants believe the specification is now in compliance with 37 C.F.R. §§ 1.821 through 1.825.

II. 35 U.S.C. § 112, Second Paragraph

Claims 37-43 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the phrase “all known polypeptides having a specified activity.” (Office action, page 3.) Applicants respectfully disagree but have amended the claims in order to further prosecution.

As amended here, independent claim 37 no longer recites the phrase “all known polypeptides having a specified activity.” Therefore, Applicants believe that pending claims 37-40 and 42-43 are in compliance with 35 U.S.C. § 112, second paragraph, and request reconsideration and withdrawal of the rejection.

III. 35 U.S.C. § 102(e)

Claims 37-40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dumas Milne Edwards *et al.* (U.S. Patent No. 7,060,479). (Office Action, page 4.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

As amended herein, claim 37 recites “A clone collection, comprising: from about 50 to about 100,000 clones, each clone comprising a nucleic acid sequence of interest, wherein the nucleic acid sequences of interest encode polypeptides.” The cited reference, Dumas Milne Edwards *et al.*, does not disclose clone collections of from about 50 to about 100,000 clones nor does it disclose suppressible stop codons. Dumas Milne Edwards *et al.* only discloses collections of clones of about 240 clones, therefore Dumas Milne Edwards *et al.* does not anticipate the currently pending claims. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) of claims 37-40.

IV. 35 U.S.C. § 103

Claims 37 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumas Milne Edwards *et al.* in view of Phillips-Jones *et al.* (*Molecular and Cellular Biology* 15:6593-6600 (1995)). (Office action, page 6.) Applicants respectfully disagree.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. (See Manual of Patent Examining Procedure (MPEP) § 2142 (eighth edition, revision 5, August 2006).) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claim 37 has been amended herein to incorporate the limitations of claim 41 and claim 41 has been canceled. As amended herein, claim 37 recites “A clone collection, comprising: from about 50 to about 100,000 clones, each clone comprising a nucleic acid sequence of interest, wherein the nucleic acid sequences of interest further comprise suppressible stop codons and encode polypeptides.” Support for the amendments to claim 37 can be found, *inter alia*, on page 44, paragraph [0149] and in original claim 41. Dumas Milne Edwards *et al.* discloses a collection of clones which encode proteins which are potentially secreted. Dumas Milne Edwards *et al.* does not discuss the use of suppressible stop codons and only discusses a clone collection of one specific size, not a range of collection sizes. Phillips-Jones *et al.* describes the generation of molecules with suppressible stop codons but does not discuss clone collections of a range of sizes. Because

neither of the cited references teach or suggest, alone or in combination, clone collections of a size of 50 to 100,000 clones, a *prima facie* case of obviousness has not been established. In view of these comments Applicants respectfully request reconsideration and withdrawal of the rejection of claim 37 under 35 U.S.C. § 103(a).

Claims 37 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumas Milne Edwards *et al.* in view of Phillips-Jones *et al.* and further in view of Stearman *et al.* (*Science* 271:1552-1557 (1996)). (Office action, page 7.) Applicants respectfully disagree.

Claim 37 recites “A clone collection, comprising: from about 50 to about 100,000 clones, each clone comprising a nucleic acid sequence of interest, wherein the nucleic acid sequences of interest further comprise suppressible stop codons and encode polypeptides.” Claim 42 further recites “wherein the nucleic acid sequences of interest comprise a tag sequence and the suppressible stop codon is located between the tag sequence and the encoded polypeptide.” Dumas Milne Edwards *et al.* discloses a collection of clones which encode proteins which are potentially secreted. Dumas Milne Edwards *et al.* does not discuss the use of a combination of suppressible stop codons and tag sequences nor does it discuss clone collections of a size of 50 to 100,000 clones. Phillips-Jones *et al.* describes the generation of molecules with suppressible stop codons but does not discuss tag sequences or clone collections of a specific range of sizes. Stearman *et al.* discloses the use of tag sequences to determine the location of proteins within a cell but does not disclose clone collections of a specific range of sizes. Because Dumas Milne Edwards *et al.*, Phillips-Jones *et al.* and Stearman *et al.* either alone or in combination do not teach or suggest, clone collections of a specific range of sizes, a *prima facie* case of obviousness has not been established. In view of these comments Applicants respectfully request reconsideration and withdrawal of the rejection of claims 37 and 42 under 35 U.S.C. § 103(a).

Claims 37 and 43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dumas Milne Edwards *et al.* in view of Senecoff *et al.* (*The Journal of Biological Chemistry* 261:7380-7386 (1986)). (Office action, page 8.) Applicants respectfully disagree.

Claim 37 recites “A clone collection, comprising: from about 50 to about 100,000 clones, each clone comprising a nucleic acid sequence of interest, wherein the nucleic acid

sequences of interest further comprise suppressible stop codons and encode polypeptides.” Claim 43 further recites “wherein the nucleic acid sequences of interest are flanked by a first and a second recombination site and the first and the second recombination sites do not recombine with each other.” Dumas Milne Edwards *et al.* only discusses homologous recombination and does not discuss site-specific recombination where the recombination sites do not recombine with each other nor does it discuss clone collections of a specific range of sizes. Senecoff *et al.* discusses the FLP recombinase protein and the recombination sites that it recognizes but it does not disclose the use of recombination sites which do not recombine with each other or clone collections of specific sizes. Because neither Dumas Milne Edwards *et al.* or Senecoff *et al.*, alone or in combination, teach or suggest clone collections of a specific range of sizes, a *prima facie* case of obviousness has not been established. In view of these comments Applicants respectfully request reconsideration and withdrawal of the rejection of claims 37 and 43 under 35 U.S.C. § 103(a).

New claim 46 recites “A clone collection, comprising: from about 50 to about 100,000 clones, each clone comprising in order, a nucleic acid sequence of interest, a suppressible stop codon and a tag sequence wherein the nucleic acid sequence of interest encodes a polypeptide.” Support for new claim 46 is found, *inter alia*, on page 44, paragraph [0149], in original claims 41 and 42 and in Figure 12C. As noted above, none of the cited references Dumas Milne Edwards *et al.*, Phillips-Jones *et al.*, Stearman *et al.* or Senecoff *et al.*, alone or in combination, teach or suggest clone collections of a specific range of sizes. Therefore Applicants believe that new claim 46 is not obvious in view of the cited references.

Conclusion

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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